EXHIBIT 1

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In re: Bair Hugger Forced Air Warming Products Liability Litigation

MDL No. 2666 (JNE/DLS)

This Document Relates to:

Nancy Axline v. 3M Co., et. al.
17-cv-00511

EXPERT REPORT OF WILLIAM R. JARVIS, M.D.

I. INTRODUCTION

This specific causation expert report concerns the perisprosthetic joint infection (PJI) suffered by Ms. Nancy Axline ("Ms. Axline"). I hereby reincorporate, in its entirety, my expert report previously provided with respect to general causation, including citations and exhibits, as if fully stated here. I also reincorporate my deposition testimony and opinions previously provided with respect to general causation.

In addition to the documents I reviewed previously for my general causation expert report, I also have reviewed the medical records of Ms. Axline cited in Exhibit A, the deposition transcripts of Drs. Wenzel, Mont, Holford, and Borak, and the supplement to the report of Said Elghobashi, Ph.D. concerning the Bair Hugger model 505. I also have reviewed the deposition transcripts of Dr. Adolph Lombardi, Dr. Nestor Narcelles, Sarah Wynn, PA-C, Ms. Axline, and Mr. Ronald Axline. In addition, there may be documents produced by Defendants and/or third parties in this matter that may impact my opinions as well. I therefore reserve the right to amend and/or supplement this report upon receipt and review of additional information obtained through such discovery.

II. BRIEF MEDICAL HISTORY OF MS. AXLINE

Based on my careful review of the records in this case, and my experience as a medical doctor and a clinician, it is my opinion to a reasonable degree of medical certainty that Ms. Axline was an appropriate candidate for her left total hip arthroplasty (THA) surgery and that the pre-operative skin preparation,surgical

antimicrobial prophylaxis, and incision care that were employed throughout the surgery complied with the standard of care.

In April 2009, Ms. Axline was a 52-year-old woman with a history of hypothyroidism, gastroesophageal reflux disease (GERD), hypertension, osteoarthritis of both hips, depression, anxiety, anemia, and dyslipidemia. She stood 5 feet 5 inches tall and weighed 198 pounds, giving her a body mass index [BMI] of 32.9. She did not have a history of past or present smoking or present alcohol use. Shehad undergone a THA procedure on her right side on February 7, 2008.

By way of background, on May 2, 2007, Ms. Axline attended a consultation with Dr. Lombardi at Joint Implant Surgeons, Inc. for evaluation of both of her hips. Ms. Axline reported she had bilateral leg pain for the past 4-5 years. There was 2+ pitting edema noted of her left lower extremity. She was observed to have a moderate limp. Her left leg was shorter than her right leg by ½ cm. X-rays of the right hip demonstrated moderate to severe joint space narrowing, bone densing, and osteophyte and cyst formation. X-rays of the left hip demonstrated mild joint space narrowing, bone densing, and osteophyteand cyst formation. She was instructed to continue conservative therapy.

Ms. Axline followed-up with Dr. Lombardi at Joint Implant Surgeons, Inc. on January 17, 2008. She reported increased pain in the right hip. X-rays of the right hip demonstrated severe joint space narrowing, bone densing, and osteophyte and cyst formation. It was noted since the last appointment her progress had deteriorated. Surgery was recommended to consist of a total right THA.

On February 7, 2008,Ms. Axlineunderwent a right THA, performed by Dr. Lombardi, at Mount Carmel Hospital. She tolerated the procedure without complications. Post-operative x-rays showed the right hip prosthesis in satisfactory position. While in the hospital she worked with physical therapy and was able to reach her goals before discharge. Ms. Axline was able to be discharged home in stable condition on February 8, 2008. No home health or outpatient therapy was needed at this point.

Ms. Axline followed-up at Joint Implant Surgeons, Inc. and saw Jeff Williams, PA-C on March 20, 2008. Her right hip incision was well healed, without signs and symptoms of infection. Ms. Axline was using a cane for ambulation, and a slight limp was observable. X-rays of the right hip revealed the right THA was in satisfactory position and alignment. She was instructed to follow-up in 12 months.

On September 19, 2008, Ms. Axline saw Dr. Lombardi, at Joint Implant Surgeons Inc. for evaluation of her left hip. She wanted to discuss scheduling of her left THA. She reported her pain was becoming severe, and she was ready to proceed with the procedure. The surgery was scheduled for January 15, 2009. At her pre-

operative physical on December 23, 2008, her laboratory results revealed her iron was low. She saw Dr. Husain, her private physician, at Harding Memorial Health-care on December 30, 2008 and was referred to Dr. Matura for evaluation of her anemia.

Ms. Axline then underwent anEsophagogastroduodenoscopy (EGD) and co-lonoscopy on January 9, 2009. These were performed by Dr. Maturu at Ohio Ma-rion Area Physicians. Her EGD showed antral gastritis and she was started on ome-prazole. Her colonoscopy revealed mild diverticulosis. A small bowel X-ray series was ordered to rule-out any mass lesions in the small bowel causing her to have blood loss. This was completed on January 12, 2009, and showed normal progres-sion through to the colon.

On February 12, 2009 Ms. Axline had an appointment with Dr. Husain at Harding Memorial Healthcare. She was using a cane for ambulation at that time and was positive for tenderness to the left hip. She was given a prescription for Percocet to help with her pain until surgery could be scheduled.

Ms. Axline was cleared to proceed with surgery on April 1, 2009 by Dr. Bloch at Mount Carmel Hospital. She was 52 years old at the time.The THA was performed on April 21, 2009 at Mount Carmel Hospital, by Dr. Lombardi.At the time of this surgery, her American Society of Anesthesiologists (ASA) score was 3. Her skin antiseptic was Chloraprep and she was given Ancef prophylactic antibiotic (2 grams) 30 minutes before her incision. She received general and spinal anesthesia and was intubated. Her surgical time was 126 minutes (2 hours and 6 minutes). An upper body Bair Hugger set to 43^{o}C was used during the procedure. Her intra-operative temperatures were all 35.8^{o}C, except for one temperature at 35.7^{o}C. Dr. Lombardi wore a sterile personal isolator suit and double gloved during the entire procedure. If lights were moved, this was done by the circulator and new sterile handles were used for each case. A pressure monitoring device monitors the air pressure in the operating room at all times. The Bovie was used approximately 2 minutes during the entire procedure. One scalpel was used for the initial incision and then a new scalpel is used for the rest of the procedure. No blood transfusions were given during the procedure. Post-operative X-rays revealed satisfactory left hip replacement. She tolerated the procedure well.Post-operatively she did have some pruritus, related to the Duramorph dressing. Pain control was initially an is-sue, but was sufficiently controlled before discharge. There also were concerns for a possible early ileus, but this was ruled-out with an X-ray of her abdomen. Through-out hospitalization,Ms. Axline worked with physical therapy and was able to meet her short term goals. Upon discharge, it was recommended that she have home health or outpatient physical therapy for continued rehab. Ms. Axlinewas discharged to home with her husband on April 24, 2009.

Ms. Axline followed-up with Jeff Williams, PA-C at Joint Implant Surgeons Inc. on May 20, 2009. Ms. Axline's chief complaint was left hip pain. It was noted she had no previous history of infection in the left hip. The left hip incision was documented to be well healed. X-rays of her left hip revealed the left THA was in satisfactory position and alignment. She was instructed to continue post-operative restrictions and to follow-up with Dr. Lombardi in two weeks. She also was instructed to not bear any weight on the left lower extremity and to use a walker.

On June 12, 2009,Ms. Axline saw Dr. Lombardi at Joint Implant Surgeons Inc. She continued to complain of left hip pain and difficult ambulation. She reported the pain as severe and constant. The left hip incision was again documented as well healed. There was mild erythema noted at the site. A moderate limp was observable with ambulation. Ms. Axline was instructed to return to the clinic in three weeks, and if her symptoms continued then review for possible revision would be needed. A prescription for Percocet 5/325 was given to her to help control her pain.

Ms. Axline continued to have left hip pain and again followed-up with Jeff Williams, PA-C on July 2, 2009, for evaluation. X-rays of the left hip did not show any changes. Ms. Axline's white blood count (WBC) was 7,300 cells/mm^3, erythrocyte sedimentation rate (ESR) was 55 (normal: 0-30), and her C-reactive protein (CRP) was 55 (normal 0-9). A WBC scan revealed 2+ uptake in the L hip "predominantly in the trochanter region". Suspecting a possible infection, an aspiration of her left hip was scheduled for July 24, 2009. This was completed and was negative (no fluid was aspirated). On August 3, 2009, a repeat WBC was 8,600, ESR 69 and CRP 73.7. Because of the rising WBC, ESR and CRP and a positive WBC scan, another left hip aspiration was performed on August 4, 2009. This aspirate showed a WBC of 80,812 cells/mm^3, 91% polymorphonuclear cells and grew out methicillin-susceptible *Staphylococcus aureus*(MSSA). The MSSA was susceptible Ciprofloxacin, Clindamycin, Erythromycin, Gentamicin, Nitrofuratoin, Oxacillin, Tetracycline, Trimethoprim-Sulfamethoxazole, Vancomycin, Levofloxacin, Daptomycin, Linezolid and Rifampin. It was resistant to Penicillin. Subsequently, Dr. Lombardi reviewed these recordsand recommended that Ms. Axline have a left hip radical debridement to treat her MSSA surgical site infection (SSI). Dr. Lombardi noted in his deposition that "there was no evidence at any time of an incisional infection.

On August 21, 2009, Dr. Lombardi performed drainage, debridement, removal of prosthesis and placement of prostalac, which is a 9x125 mm Biomet cement spacer mold using Cobalt cement with 3 grams of vancomycin and 3.6 grams of tobramycin per unitto her infected left THA. There is no mention of any discharge or pus at the incision or anterior to the fascia. The femoral component and canal were debrided. Ms. Axline tolerated the procedure well. During the hospitalization, on August 22, 2009, Dr. James Smith frominfectious diseases was consulted to assist in the management of her intravenous (IV) antibiotics. She did have complaints of calf tenderness, but a Duplex Ultrasound ruled out any abnormalities. Ms. Axlinealso

was seen by physical therapy during her hospitalization. A PICC line was placed on August 24, 2009 for continued IV antibiotic therapy (i.e., Ancef 2 grams q 8 h). She was determined to be stable for discharge on August 25, 2009. Home health services were arranged through Marion General Hospital for continuation of her IV antibiotic therapy.

On September 18, 2009 Ms. Axline was seen at Mount Carmel Hospital by Derrick Johnson, MD at the request of Dr. Lombardi for medical clearance before her left hip re-implantation. She was cleared for surgery. This same day, she followed up with Dr. Lombardi at Joint Implant Surgeons Inc. At this point, she continued on IV antibiotic therapy (Ancef). Her staples were removed this visit without complications. Re-implantation of her left hip was scheduled for October 5, 2009.

Ms. Axlineunderwent the second of the two-stage revision surgeries on October 5, 2009 at Mount Carmel Hospital by Dr. Lombardi. At the time of this surgery, her American Society of Anesthesiologists (ASA) score was 2. Again, she had Chloraprep antisepsis and received Ancef (2 grams) and gentamicin (80 mg) surgical antibiotic prophylaxis approximately 21-57 minutes before her incision. She tolerated the procedure well and there were no complications. Post-operative x-rays revealed normal alignment status post THA revision on the left. Intra-operative cultures were negative. Her peripherally inserted central catheter (PICC) line was replaced during the hospitalization. She was again consulted by infectious disease, it was determined at that point to continue her on IV Ancef for a short time and if her wounds healed nicely, she would be switched to Keflex. Ms. Axline also required 1 unit of packed red blood cells due to her hemoglobin being low before discharge. Ms. Axlineworked with therapy and met her goals with assistance of her husband for all transfers. She was determined to be stable for discharge on October 7, 2009. Home health services were again arranged through Marion General Hospital.

On October 27, 2009,Ms. Axline followed-up with Jeff Williams, PA-C at Joint Implant Surgeons Inc. Her staples were removed without complications. She was instructed to do toe touch weight bearing until follow-up in three weeks. She had this follow-up on November 18, 2009. Her incision site on her left hip was documented to be well-healed. X-rays of the left hip revealed her THA in satisfactory position and alignment. Her diagnosis were osteoarthritis of the left hip status post THA on the left, failed THA due to infection/inflammation of prosthesis of the left hip, and status post left hip radical debridement with left hip re-implantation. Ms. Axline was instructed to continue post-operative restrictions. She was released to return to work on December 21, 2009. Ms. Axline was to continue 25% weight bearing for one week, 50% for one week, 75% for one week, and then 100%.

Ms. Axline returned to Joint Implant Surgeons Inc. and saw Jason Hurst, M.D. on March 20, 2012 for her annual exam. She reported she had recently had multiple falls, which had aggravated her left hip symptoms. A slight limp was ob-

served with ambulation. X-rays of the bilateral hips showed satisfactory position and alignment. Outpatient therapy was recommended. She also underwent an evaluation of her right shoulder on this date. Ms. Axline reported she had had right shoulder pain for years, but it has progressively worsened. An X-ray of right shoulder demonstrated mild, joint space narrowing, bone densing, and osteophyte formation. She was diagnosed with osteoarthritis of her right shoulder. She was administered a Kenalog intra-articular injection to her right shoulder. She was instructed to follow-up in 6 months.

It is my opinion to a reasonable degree of medical certainty that the standard of care was employed throughout the above surgeries and hospital stays.

In follow-up visits from October 2009 through 2012, Ms. Axline presented well with negative x-rays and only occasional pain (1-2/10 on pain scale). The index left THA infection was diagnosed and treated properly, and ultimately was successfully resolved.

Conclusion and Synopsis of Key Opinions

All the opinions I express in this report are opinions I hold to a reasonable degree of scientific and medical certainty.

On April 21, 2009, Ms. Axline underwent a left THA procedure (i.e., index procedure). Her pre-operative skin preparation (i.e., Chloroprep) and prophylactic antimicrobial agent, dose, and timing (i.e., 2 grams of Ancef administered 30 minutes before incision) were consistent with applicable guideline recommendations and followed appropriate standards of medical practice at all times. The duration of the initial implant surgery was 78 minutes. Regional spinal anesthesia without endotracheal intubation was given. The estimated blood loss was 175 ml and no blood transfusions were given. The nursing operating room records indicate: "No break in sterile technique; No apparent cross –contamination; Aseptic technique maintained; Copious wound irrigation implemented; Implementedimplant protocol; Minimal handling of implant prior to placement". I am unaware of any reports of contaminated surgical tools or supplies, nor any deviations from standard surgical practice or infection control procedures. Based on my review of available records, the medical care comported with all accepted standards of medical and surgical practice.

Despite the appropriate care provided by the medical care professionals, approximately 3weeks after the left THA (May 20, 2009), Ms. Axline returned to Dr. Lombardi complaining of pain, at this and subsequent evaluations (i.e., June 12, 2009, July 2, 2009, and July 24, 2009). no incisional infection was noted. On July 2, 2009, an elevated ESR and CRP were detected. On July 7, 2009, an abnormal WBC scan—with 2+ uptake in the femoral trochanter region--was found. Subsequently (on August 3, 2009), the WBC, ESR and CRP continued to rise and on August 4,

2009an aspirate of the left hip revealed elevated WBCs, mostly polmorphonuclear cells, and the culture grew MSSA. Despite noting on July 31, 2009 that "left hip incision is well healed", a deep MSSA-SSI was suspected and documented at the August 21, 2009 left THA revision surgery, when the prosthesis was removed and an antibiotic spacer was inserted and Ms. Axline began a 6 week course of IV antibiotic therapy. At the time of this prosthetic joint infection (PJI), there was no documentation of any incisional or pre-fascia SSI (i.e., superficial or incisional SSI).Thus, four months after the index procedure, Ms. Axline was diagnosed with a MSSA-PJI which necessitated an incision and drainage (I&D), a two-stage revision surgery including removal of herleft THA prosthesis, and placement of an antibiotic spacer followed by six weeks of antimicrobial therapy with agents targeting MSSA. After the infection cleared, a permanent hip prosthesis was re-implanted (October 5, 2009). The findings of an elevated ESR and CRP, abnormal WBC scan, positive left hip aspirate culture for MSSA, and evidence of PJI at the time of the I&D surgery, along with Ms. Axline's response to antimicrobial therapy, are all consistent with a nosocomial intra-operatively acquired MSSA-PJI.

III. METHODOLOGY

Medical care providers routinely use a causation assessment that courts refer to as a "differential diagnosis" or "differential etiology" in assessing the cause of a patient's medical condition. Regardless of its name, this methodology requires "ruling in" all potential causes of the condition and then "ruling out" unlikely causes of the condition. In the Bair Hugger litigation, the proper, generally accepted methodology requires ruling in all potential causes of the bacteria inoculating the joint and then ruling out unlikely causes of the bacteria that inoculated the joint based on the facts and evidence in each case. As to biological plausibility, bacteria are the actual ***causes*** of the PJI; that is, the only biological causes of infection are bacteria that have inoculated the joint during exposure at the time of surgery. The determinative issue is the most likely ***mechanistic source*** of the bacteria that inoculated the joint.

Using the foregoing method to identify potential causes for Ms. Axline's MSSA-PJI, the medical literature confirms that the majority of PJIs are caused by pathogens that are deposited in the surgical incision during the surgery.[1] Put simply, without microbial pathogens and dissemination to the deep joint space, ***no patient*** would suffer a PJI regardless of how many risk factors he or she may possess or his or her susceptibility to infection.[2] While it is true that Ms. Axline—like nearly all

[1]*See* Jarvis General Causation Expert Rpt. at 4–8, 16 (collecting scientific sources).
[2]As discussed during my deposition, these "risk factors" do not ***cause*** PJI, but rather may increase the likelihood that PJI ***will develop*** if bacterial contamination of the

patients—had several risk factors for potential infection, including obesity, it is my clinical and professional medical opinion that none of these conditions impacted her development of PJI.

Based on my review of the medical records in this case, my differential diagnosis/etiology confirms that the care rendered to Ms. Axline, the practices of the surgical team, the operating room conditions and environment, and other applicable factors, together with the medical literature concerning forced air warming technology and Bair Hugger warming specifically, and the mechanistic Computational Fluid Dynamics (CFD) study performed by Dr. Elghobashi, the most likely source of Ms. Axline's MSSA-PJI was the inoculation of her surgical wound at the time of her index surgery on April 21, 2009.

Knowing the overwhelming majority of PJIs are caused by bacteria deposited during surgery, I turn to the potential sources of pathogens inside the operating room. Relevant medical literature confirms that the vast majority of bacteria, often measured as CFUs, in the operating room come from the surgical team.[3]

A. Rule In / Rule Out: Potential Causes of Bacteria Contaminating the Joint

1. Bair Hugger

The Bair Hugger significantly increases the quantity of particles and bacteria over the sterile surgical field resulting in a significantly increased risk of PJIs as previously outlined in my general causation expert report and deposition. *It is my expert opinion to a reasonable degree of medical certainty that when a Bair Hugger blanket is used during orthopedic arthroplasty surgeries, it substantially increases the risk of a PJI.*

The following points support my opinion that the Bair Hugger significantly increases risk of PJIs:

- As outlined in my expert report on general causation, a thorough review of the peer-reviewed medical literature, including the elevated

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prosthesis/joint/incision occurs. Indeed, offending pathogens or colony forming units (CFUs) of the organism must not only exist, but such pathogens must deposit at the surgical site in the prosthesis/deep joint space in order for a PJI to occur at the time of surgery.

[3]*See* Jarvis General Causation Expert Rpt. at 5 (citing, *e.g.*, Whyte 1988) *see also id.*at 21 (noting patient-specific interventions that reduce likelihood of patient as cause).

odds-ratio reported in the McGovern study, together with various case reports.

- The expert CFD report prepared by Dr. Said Elghobashi regarding the Bair Hugger 750,[4] along with his supplemental report regarding the impact of the Bair Hugger 505, on the operating room unidirectional airflow. According to Dr. Elghobashi's study and the videos generated as part of that study, the Bair Hugger causes significant disruption of operating room airflow, leading to increased number of skin squames over and in the sterile field.

- As further detailed in my general causation report, the Bair Hugger has two mechanisms for contaminating the operative field with bacteria—through blowing non-filtered, non-sterile air and through releasing excess heat that disrupts operating room airflow. Each mechanism causes increased squames and therefore bacteria over the sterile field.

2. Heating Ventilation and Air Conditioning (HVAC) System

Based on my experience and conducting outbreak investigations for the Centers for Disease Control and Prevention (CDC), the HVAC of the operating room is a potential source of airborne contamination. Based on the limited documents received from Mount Carmel East Hospital, the operating room used by Dr. Lombardi in performing Ms. Axline's THA was the same as designed in 2003. It used a unidirectional airflow system with a two-filter system. Records do not show that the HVAC system was impaired or contaminated. Thus, the properly-functioning HVAC system could not have increased Ms. Axline's risk of developing a PJI. It is my professional opinion that it did not increase the risk.

3. Surgical Team Contamination

The surgical team, if not properly scrubbed in, may contaminate the sterile field and increase the risk of infection, including increasing the risk for PJI during THA. Records do not show that the surgical team failed to follow the appropriate aseptic procedures and sterile techniques. The surgical personnel in the operative field all wore sterile single use personal isolator suits with their own air supply. Absent evidence to the contrary, the surgical team complied with appropriate

[4] This work has since been published in an internationally renowned, peer-reviewed journal. He X, Karra S, Pakseresht P, Apte SV, Elghobashi S. *Effect of heated-air blanket on the dispersion of squames in an operating room*.INT J NUMER METHOD BIOMED ENG. 2018;34:e2960

standards of care, rendering the likelihood of the surgical team's contaminating the wound very small. It is my professional expert opinion that the surgical team did nothing to increase the risk of infection during Ms. Axline'ssurgery and that her infection was not the result of any action or inaction by this team.

4. Patient's Flora

One of the potential sources of bacteria is the patient's flora at or immediately adjacent to the surgical incision. However, there is a general consensus that PJIs are caused by airborne contamination and by direct contact by the patient's own flora.[5] The use of Chloroprep (i.e., 2% chlorhexidine and 70% isopropyl alcoholas skin preparation would nearly eliminate skin flora at the surgical incision site and therefore the likelihood of the PJI being caused by the patient's own flora around the surgical site is very unlikely. Ms. Axline's own flora can thus be ruled out. Such skin flora is more commonly associated with superficial or incisional SSIs, which Ms. Axline did not have.

5. Surgical Procedure and Technique

Based on my review of the medical records, it is evident that the surgeons and staff followed appropriate standards of care and proper surgical procedure and technique. Dr. Lombardi testified that he practices sterile technique, including during Ms. Axline's surgery.[6]There is no evidence that at any time of the procedure there was a break in the sterile field by any procedure or technique documented in the medical records. Without the deposition testimony of the surgical team and staff, there is no evidence that anything occurred outside what is mentioned in the medical records or Dr. Lombardi's or Dr. Narcellas' depositions. There was no evidence of any contamination of the surgical instruments or iatrogenic contamination of the sterile field. Based on the records reviewed, it is my opinion held to a reasonable degree of medical certainty that the surgical procedure and technique was within the standard of care and that likelihood of the surgical procedure or technique of the surgical team causing bacteria to inoculate the joint is very low. The surgical procedure and technique can therefore be ruled out as a likely cause.

6. Other Potential Causes

Based on the medical records, literature, and previously disclosed opinions of Defendants' experts, I have compiled the list above regarding potential causes of

[5] *See, e.g.*, PROCEEDINGS OF THE INTERNATIONAL CONSENSUS MEETING ON PERI-PROSTHETIC JOINT INFECTION (2013) at 115–16 ("[T]he focus of our recommendation is to reduce the volume of bacteria in the operating room with particular attention to airborne particles.").

[6] Lombardi Dep. 93:24-94:2.

bacteria reaching the sterile field. There is no peer-reviewed published literature to support that cabinets, lights, tables, computers, or narcotics increase the risk of PJI. I reserve the right to supplement this section and report if any new information should arise from the depositions of fact witnesses or other discovery regarding this matter.

7. Possible Causes Not Ruled In

In light of my review of Defendants' expert reports on general causation, and the depositions of Drs. Wenzel and Mont, I have considered the following possible causes identified by Dr. Mont and have not ruled them in as plausible sources that can cause bacteria to inoculate the joint or other areas of the sterile field: anesthesia machines; surgical lights; computer monitors; computer consoles; electrocautery devices; bovie; surgical drapes; cabinets along the walls; the suction drain; sterilized surgical equipment; drop buckets; trash receptacles; or surgeons moving their hands.[7] Based on my review of the literature, my training, education, and experience, I agree with Defendants' expert Dr. Wenzel that there is no evidence in the scientific community indicating that any of the foregoing variables increase the likelihood of bacteria inoculating the joint.[8]

Further, in light of my review of the deposition of Dr. Lombardi, I agree there is no evidence that Ms. Axline had a superficial incisional wound infection,[9] or any other type of ongoing infection that could have caused the PJI,[10] and that there is no evidence her PJI was caused by the trash bin in the operating room,[11] the Bovie machine,[12] chairs in the operating room,[13] or the cabinets in the operating room.[14] Dr. Lombardi agreed there is no evidence that the tools, implant, gowns, drapes, or anything else used during Ms. Axline's surgery was contaminated.[15] Dr. Lombardi testified there is no evidence that his gloves were perforated at any time during Ms. Axline's surgery.[16] Dr. Lombardi testified that one of the purposes of the laminar screen in the operating room where Ms. Axline's surgery took place was to

[7] *See, e.g.*, Mont General Causation Expert Rpt. at 10–11.
[8] *See, e.g.*, Wenzel Dep. at 99:4-104:2.
[9] *See, e.g.*, Lombardi Dep.At 90:11-20.
[10] Lombardi Dep. 94:16-23. Also no evidence that Ms. Axline had any infection, including a urinary tract infection Lombardi Dep. 94:24-95:3, or any dental work that would cause an infection. Lombardi Dep. 95:4-9.
[11] Lombardi Dep.At 92:12-16.
[12] Id. at 92:17-19.
[13] Id. at 92:20-21.
[14] Id. at 92:23-93:2.
[15] Dep. 95:9-15.
[16] Lombardi Dep. 93:14-20.

minimize the airborne contamination over the sterile field.[17] Dr. Lombardi testified if the sterile field was contaminated during Ms. Axline's surgery, it would have been noted either by himself or a member of his team in Ms. Axline's medical record,[18] and that there is no evidence that the sterile field was in any way contaminated or compromised during Ms. Axline's primary left hip surgery.[19] Additionally, I agree with Dr. Lombardi that post-operative SSIs, like the one Ms. Axline was diagnosed with, are believed to occur via bacterial inoculation at the time of surgery or as a result of bacterial contamination of the wound via open pathways to the deep tissues layers.[20]

B. Bair Hugger is the Most Likely Cause of Bacteria Inoculating the Joint

1. Methodology using Relative Risk and Differential Etiology

Differential diagnosis and/or etiology often use epidemiological studies and relative risk ratios to determine causation in a specific case. As discussed below, numerous studies, including the McGovern study, indicate directly and indirectly that the Bair Hugger more than doubles the risk of PJI. A relative risk ratio of 2.0 in and of itself shows that the device or drug at issue is the most likely cause of the disease. Thus, I agree with Defendants' expert Dr. Holford that a relative risk ratio >2.0 indicates that a device or drug is the most likely cause of the disease.[21] Thus, absent any deviation from the standard of care by the physicians, staff, or hospital, the Bair Hugger is the most likely cause of a patient's PJI in an orthopedic arthroplasty surgery.

In the case of Ms. Axline, I have analyzed all other plausible causes of a PJI in surgery and have used her medical records to rule out those variables as the most likely cause of her implant being inoculated with bacteria causing her PJI. The McGovern study and/or Dr. Elghobashi's CFD model paired with the Stocks and Darouiche studies each independently confirm that the Bair Hugger is the most likely cause of Ms. Axline'sPJI.

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[17] Lombardi Dep. 89:13-17.
[18] Lombardi Dep. 93:3-13.
[19] Lombardi Dep. 93:9-13.
[20] Lombardi Dep. 87:19-88:7.
[21] At his deposition, Dr. Holford agreed that "[i]f the incidence of disease in an exposed group is more than twice the incidence in the unexposed group, the probability that exposure to the agent in a similarly situated individual is also greater than 50%." *See* Holford Dep. at 225:19-226:1. The Reference Manual states as much. *See, e.g.*, REFERENCE MANUAL ON SCIENTIFIC EVIDENCE, 3d ed. at 612 (Federal Judicial Center).

2. Quantifying the Risk Posed by Bair Hugger

CFD Model and Peer-Reviewed Literature

The results of Dr. Elghobashi's CFD test makes clear that the Bair Hugger causes significant turbulence in the operating room, particularly around the operating room table. As a result of that disruption, the Bair Hugger significantly increases the number of skin squames reaching the surgical site, the operating room table, and side tables where instruments, fluids, and implants are located. Indeed, the Bair Hugger increases the density of particles large enough to carry bacterial CFUs by more than 10 CFU/m^3 in a very short time: less than a minute after the Bair Hugger reaches the appropriate temperature for warming patients.

The International Consensus of Orthopedic Surgeons (ICOS), along with a large body of medical literature, confirms that the probability of PJI correlates directly with the quantity of bacteria that reaches the surgical wound during an orthopedic arthroplasty procedure. The literature also demonstrates that use of the Bair Hugger increases particles over the sterile field. The overwhelming number of particles in the operating room are from the surgical staff and patient. A range of at least 1 million to as much as 900 million skin squames are shed, per hour, by surgical staff during a typical procedure. As confirmed by Dr. Wenzel, many of these particles carry bacteria.[22]

As discussed in my general causation report, the Stocks and Darouiche studies correlate particles and CFU over the surgical site. Stocks et al. correlated the number of CFUs with the number of 10 micron particles, while Darouiche et al. correlated the number of CFUs with the incidence of PJI in orthopedic procedures. Based on the empirical data collected in the Darouiche study, the authors ultimately concluded that for every increase of 10 CFUs/m^3 there was a doubling of the risk of PJI.[23]

Given Dr. Elghobashi's CFD test, along with the results of the Stocks and Darouiche studies, use of the Bair Hugger during the surgery of Ms. Axlineis the most likely cause of the bacteria inoculating the joint and thus the cause of PJI in this case.

The McGovern Study

As previously stated in my general causation expert report, the McGovern study reports a relative risk ratio (odd ratio) of 3.8 comparing use of Bair Hugger to conductive blankets in arthroplasty surgeries. However, relying on a draft data set,

[22] *See* Wenzel Dep. at 50:16–21 ("Forty percent of particles can carry bacteria.").
[23] *See* Jarvis General Causation Expert Report at 24 (citing Stocks and Darouiche).

Defendants' experts assert that the odds ratio is 2.8 rather than 3.8. Whether one uses the published data in the McGovern study or the draft data used by Dr. Holford, the evidence shows more than a doubling of the risk (RR of ≥ 2.0) when the Bair Hugger forced air warmer is used compared to non-forced air warming devices such as conductive blankets. The risk ratio reported by McGovern et al. further shows that Bair Hugger is the most likely cause of bacteria inoculating the implant.[24] Under normal operating room and surgical procedures, the most likely cause of Ms. Axline'sPJI was thus the Bair Hugger.

IV. CONCLUSION

In summary, I have conducted a careful and thorough medical record review allowing me to provide the Court with a causation assessment and/or differential diagnosis and/or differential etiology for Ms. Axline's PJI. As part of my methodology and process in this case, I have ruled out all other potential causes of infection and determined that the Bair Hugger is the most likely cause of Ms. Axline's PJI. In doing so, I have considered all medical evidence made available to me, as outlined herein, and also have reviewed all countervailing possibilities that might be postulated based on Ms. Axline's pre-existing medical conditions as well as the conditions and practices prevailing at the hospital and operating room at the time of herleft hip index surgery.

Using this careful, deliberative, well-accepted methodology, comparing Ms. Axline'smedical history to other infection cases I have seen over my career, and based on my review of all of the medical and scientific papers addressing these issues, as well as my own scientific training, knowledge, and clinical experience, I conclude to a reasonable degree of scientific and medical certainty that Ms. Axlinedeveloped anMSSA-PJI after herleft THA procedure on April 21, 2009, and that MSSA was inoculated into her operative wound directly or indirectly by the Bair Hugger.

Moreover, based on the available medical records and literature, CFD testing, including Dr. Elghobashi's peer reviewed publication and the videos he generated as part of his large-eddy simulation (LES) CFD study, the expert report of Dr. Samet, the 3.8 odds-ratio reported in the McGovern study and by Dr. Samet, which can be used to demonstrate specific causation, the deposition testimony of Dr. Holford, and other available data discussed in this report and my general causation report, it is my opinion within a reasonable degree of medical certainty that use of the Bair Hugger in Ms. Axline's index surgery was the most likely cause of the bacterial exposure that contaminated herleft hip prosthesis in this case.

[24] *See, e.g.*,Holford Dep. at 225:19-226:1.

Dated: August 13, 2018

William R. Jarvis, M.D.

Appendix A

1. Depositions of Dr. Narcelles, Dr. Lombardi, Mrs. Axline, Mr. Ronald Axline, and Sarah Wynn, PA-C.

2. Selected medical records of Mrs. Axline:

a. Consent form for left total hip arthroplasty (THA) on 4-21-2009.

b. Operative report for left THA on 4-21-2009.

c. Anesthesia report for left THA on 4-21-2009.

d. Nursing pre-admission record for left THA on 4-21-2009.

e. Nursing intra-operative record for left THA on 4-21-2009.

f. Consent for left THA revision 10-5-09.

g. Anesthesia pre-operative evaluation for left THA on 10-5-09.

h. Anesthesia record for 10-5-09 left total hip arthorplasty (THA).

i. Nursing intraoperative record forleftl THA revision on 10-5-2009.

i. Post-operative flow sheet for left THA on 10-5-2009,.

j. Infectious disease medical records from 8-22-09 to 11-24-09.

k. Joint Implant Surgery, Inc. medical records.

l. Medical records for Mt. Carmel New Albany Surgical Center (February 7, 2008 through October 7, 2009.

3. Scholten R, et al. The incidence of mild hypothermia after total knee or hip arthroplasty: A study of 2600 patients. J of Orthopedics 2018;15:408-11.

4. Medical chronology of Mrs. Nancy Axline from 1/30/2002 through 4/17/2017.